OMEGA MEDICAL IMAGING, INC. K050092

510(k) SUMMARY

JAN 3 1 2005

Company Name:	Omega Medical Imaging, Inc
Address:	675 Hickman Circle Sanford, FL 32771
Telephone No:	407-323-9400
Registration No.:	1052701
Contact person:	James A. Princehorn
Date Prepared	3 January 2005
Device (trade) name:	Automatic Beam-limiting Device Model R605FACS
Classification name:	Diagnostic X-Ray Beam-Limiting Device (21 CFR 892.1610) Class II (Procode: 90 IZW)
Common/usual name:	Automatic Radiographic/fluoroscopic Collimator

Predicate device:

- Dunlee automatic "FORMAT A" collimator manufactured by Philips Medical Systems legally marketed under number K031597.
- Advantech Model R600/800 series collimators manufactured by RALCO S.R.L legally marketed under number K904182

Device description:
The Omega R 605FACS is an automatic collimator designed for use in diagnostic radiographic/fluoroscopic applications. It includes round field shutters and an additional lung filter for cardiac application.

Intended use:

- The Omega R605 FACS automatic collimator is intended for use in diagnostic radiographic/fluoroscopic applications.

Safety information:

- The Omega R605 FACS collimator will comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega R605 FACS collimator will comply with the international safety standards IEC 60601-1, IEC 60101-1-2, and IEC 60601-1-3.
- The Omega R605 FACS will comply with CE Marking requirements.
- The Omega R605 FACS will comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Conclusion:
The Omega R605 FACS collimator does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the R605 FACS collimator to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

Mr. James A. Princehorn
President
Omega Medical Imaging, Inc.
675 Hickman Circle
SANFORD FL 32771

Re: K050092
Trade/Device Name: Omega R605 FACS automatic collimator
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray Beam-limiting device
Regulatory Class: II
Product Code: 90 IZW
Dated: January 5, 2005
Received: January 14, 2005

Dear Mr. Princehorn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Omega Medical Imaging, Inc.

K050092

Omega R605 FACS Collimator

Indications for Use:

The Omega R605 FACS automatic collimator is intended for use in diagnostic radiographic/fluoroscopic applications.

Prescription Use ✓

David G. Jayne

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050092